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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/524,422	03/11/2000	Randall W. Nelson	530-006	6081

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EXAMINER	
COUNTS, GARY W	
ART UNIT	PAPER NUMBER

1641  
DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	Applicant(s)	
	NELSON, RANDALL W.	
Examiner	Art Unit	
Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 28 February 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 1,3-5,7 and 9-22 is/are pending in the application.

4a) Of the above claim(s) 9-22 is/are withdrawn from consideration.

5) Claim(s) 1,3-5 and 7 is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) Other:

## DETAILED ACTION

### Status of the claims

The amendment filed February 28, 2003 is acknowledged and has been entered.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 5 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 5 & 7 recite the limitations that the filter element is securely fixed to the tip and that the filter element is removably fixed within the tip. On pages 40-41 applicant disclose beads having affinity reagent immobilized thereon and Applicant discloses slurried affinity reagent incubated with specimen and internal reference. Applicant also disclosed the affinity reagent contains myotoxin a affinity bound to the retain anti-myotoxin a, which was physically separated from the specimen by forcing the volume through the backside of a P-10, 10 $\mu$ L filter pipette tip thereby retaining the affinity reagent on the filter. The applicant does not disclose that the filter element is securely fixed to the tip or that the filter element is removably fixed to the tip.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1, 3 and 4 rejected under 35 U.S.C. 102(a) as being anticipated by Bieber et al (mass Spectrometric Immunoassay, Anal. Chem. 1995, 67, 1153-1158).

Bieber et al disclose a filter pipette tip having an affinity reagent (beads containing immobilized antibodies) present within the tip (p. 1154 experimental section, see also figure 1).

5. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Ollington et al (US 5,403,745).

Ollington et al disclose a pipette comprising antibodies immobilized to beads (solid substrate). Ollington et al also disclose a pipette tip having a filter (col 13).

6. Claims 1 and 3-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Wainwright et al (WO 94/20831).

Wainwright et al disclose a micropipette tip having a porous element (filter element) (fig 3) (31). Wainwright et al disclose fiber layers retained on top of this porous element. Wainwright et al disclose that antibodies are immobilized on these fiber layers. Wainwright et al disclose that the porous element is securely fixed to the tip (p. 5).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bieber et al in view of Raybuck et al (US 5,833,927)

See above for teachings of Bieber et al.

Bieber et al differ from the instant invention in failing to disclose the filter element is removably fixed within the tip.

Raybuck et al disclose a micropipette tip comprising a porous membrane (filter element) that may be made peelable from the pipette tip for subsequent processing.

It would have been obvious to one of ordinary skill in the art to incorporate a peelable filter such as taught by Raybuck et al into the device of Bieber et al because Raybuck et al shows that this provides for a device for capturing a component present

in a fluid and provides the advantage of capturing the desired component on or at or in the forward-facing surface of the membrane thus allowing for easy access for subsequent treatment.

***Response to Arguments***

9. Applicant's arguments filed February 28, 2003 have been fully considered but they are not persuasive.

Applicant's argue that the amendments to claims 2 and 5-8 make moot the 35 U.S.C. 112 first paragraph rejection directed toward subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. The cancellation of claims 2, 6, and 8 which recited "affinity reagent is bound to a filter element" renders the argument moot. However, Applicant failed to respond to the 112 first paragraph rejection concerning the recited limitations in the claims that the filter element is securely fixed to the tip or that the filter element is removably fixed to the tip. Therefore, the 112 first paragraph rejection of claims 5 and 7 is maintained.

Applicant argues that the Bieber et al reference cited by the Examiner does not constitute a description of the invention in a printed publication before the invention was made by Applicants in that Applicants are the authors of the journal article, and Applicants conceived their invention before the publication of the Bieber et al reference. This is not found persuasive because Applicant has not submitted a declaration that demonstrates that Allan L. Bieber did not take part in the conception of the subject

matter disclosed and claimed in the instant patent application, nor did Applicant disclose the work performed by Allan L. Bieber in connection with the instant reference. Therefore, the statement that Applicants are the authors of the journal article and Applicants conceived their invention before the publication of the Nelson et al reference is not found persuasive.

***Conclusion***

10. No claims are allowed.
11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

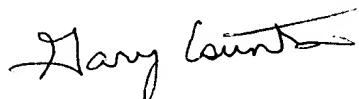
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts  
Examiner  
Art Unit 1641  
April 17, 2003



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNICAL CENTER 1600  
04/18/03